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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,941	09/11/2003	Richard C. Potter	BASIC.034DV1C1	5072

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EXAMINER	
HENRY, MICHAEL C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/659,941	POTTER ET AL.	
	Examin r	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 02/27/06.

The amendment filed 02/27/06 affects the application, 10/659,941 as follows:

Claims 1, 12-22 and 42 have been amended. This leaves claims 1-52.

The responsive to applicants' amendments is contained herein below.

Claims 1-52 are pending in application

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 22-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 1, applicant claims "A physiologically acceptable concentrated beta-glucan composition comprising a glucan having a mixed β(1,3)(1,4) linked glucopyranosyl backbone prepared in an alcohol free process in the absence of organic solvents, wherein said beta-glucan composition has a concentration greater than 16% by weight." However, the recitation of the language "16% by weight" in the claim constitutes new matter as set forth in the claim. More specifically, the specification does not describe, disclose, provide or use any language or matter that pertains to 16% by weight of any beta-glucan composition, as recited in the claim. Furthermore, the introduction of the said language "16% by weight" as set forth in claim 1,

constitutes new matter. On the contrary, it should be noted that the specification describes beta-glucan compositions comprising between about 30% weight and about 100% weight, between about 50% and about 95% and between about 60% and about 90% (see page 4, [0023]). Moreover, the specification does not have support for the said language and consequently the claims contain new matter. Similarly, in claim 32, the language, phrase or limitation "7% by weight" is also new matter. It should be noted that applicant states (in the Background of the invention) that oat bran is defined as containing a minimum of 5.5% by weight beta-glucan, and typically contains up to 6% or 7% by weight beta-glucan (see last three line of page 1 of the specification) but, applicant does not disclose that any of their compositions has a concentration of 7% by weight of the beta-glucan. Dependent claims 2-10 and 23-52 which are drawn to said beta-glucan composition, are also encompassed by the aforementioned rejections.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-21, 32-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al. (US 5,512,287).

Claim 1 is a product-by-process claim wherein the applicant claims "A physiologically acceptable concentrated beta-glucan composition comprising a glucan having a mixed β(1,3)(1,4) linked glucopyranosyl backbone prepared in an alcohol free process in the absence of organic solvents, wherein said beta-glucan composition has a concentration greater than 16% by

weight." Wang et al. disclose applicant's beta-glucan composition comprising a glucan having a mixed β(1,3)(1,4) linked glucopyranosyl backbone, wherein said beta-glucan composition has a concentration about 60-90% by weight (see abstract and example 1, col. 4, line 50 to col. 5, line 14). A quotation from the MPEP (Manual of Patent Examining Procedure, 8 ed., August 2001) pertaining to Product-by-Process Claims is given below in order for further corroborate the reason for the aforementioned rejection. The quotation states that " PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)." Claims 2-8 which drawn to beta-glucan of claim 1 are also product-by-process claims which are rejected as being anticipated by Wang et al. (see abstract and example 1, col. 4, line 50 to col. 5, line 14). Claim 9 which is drawn to the composition of claim 1, wherein said beta- glucan is selected from those obtainable from oats, barley ....., is rejected by as being anticipated by Wang et al. (see abstract and example 1, col. 4, line 50 to col. 5, line 14). It should be noted that the source from which the beta-glucan is obtained does not add to the patentability of the composition. Moreover, the source from which the said beta-glucan is obtained does not limit the claimed composition. It should also be noted that Wang et al.'s composition comes from oats oats (see abstract and example 1, col. 4, line 50 to col. 5, line 14). Claim 10 which is drawn to the composition of claim 1, wherein said glucan

is formulated for oral administration is also rejected by Wang et al., since applicant's claimed composition does not disclose any ingredient or substance that renders it different from Wang et al.'s composition or unsuitable for oral administration. In fact, Wang et al.'s composition comes from oats which is edible (see abstract and example 1, col. 4, line 50 to col. 5, line 14). Claims 11-19, which are drawn to a composition for reducing low density lipoprotein and total serum cholesterol comprising concentrated beta-glucan are product by process claims which are anticipated by Wang et al., since applicant's claimed dietary supplement composition does not recite any ingredient or substance that renders it different from Wang et al.'s composition. It should be noted that the source from which the beta-glucan is obtained does not add to the patentability of the composition. Furthermore, the said packaging, labeling and the intended use of the composition does not add to the patentability of the composition. Claim 20, which is drawn to the composition of claim 11, wherein said beta- glucan is selected from those obtainable from oats, barley ....., is rejected by as being anticipated by Wang et al. It should be noted that the source from which the beta-glucan is obtained does not add to the patentability of the composition. Moreover, the source from which the said beta-glucan is obtained does not limit the claimed composition. It should also be noted that Wang et al.'s composition comes from oats (see abstract and example 1, col. 4, line 50 to col. 5, line 14). Claim 21 which is drawn to the supplement of claim 11, wherein said beta glucan is formulated for oral administration, is rejected as being anticipated by Wang et al. since applicant's claimed composition does not disclose any ingredient or substance that renders it different from Klein's composition and suitable for oral administration. In fact, Wang et al.'s composition comes from oats which is edible oats (see abstract and example 1, col. 4, line 50 to col. 5, line 14).

Claims 32-40 which are drawn to a composition comprising concentrated (1,3)(1,4) beta glucan with a food product are product-by-process claims which are anticipated by Wang et al., since Wang et al.'s composition is also in combination with a food (oats) oats (see abstract and example 1, col. 4, line 50 to col. 5, line 14). Claim 41 which is drawn to the composition of claim 32, wherein said beta- glucan is selected from those obtainable from oats, barley ....., is rejected by as being anticipated by Wang et al. It should be noted that the source from which the beta-glucan is obtained does not add to the patentability of the composition. Moreover, the source from which the said beta-glucan is obtained does not limit the claimed composition.

Claims 42-50 which are drawn to a pharmaceutical composition comprising concentrated (1,3)(1,4) beta glucan and a pharmaceutically acceptable carrier are product-by-process claims which are anticipated by Wang et al., since Wang et al.'s composition also contain water which is a pharmaceutically acceptable carrier oats (see abstract and example 1, col. 4, line 50 to col. 5, line 14). It should be noted that the source from which the beta-glucan is obtained does not add to the patentability of the composition. Claim 51 which is drawn to the composition of claim 42, wherein said beta- glucan is selected from those obtainable from oats, barley ....., is rejected by as being anticipated by Wang et al. (see abstract and example 1, col. 4, line 50 to col. 5, line 14). It should be noted that the source from which the beta-glucan is obtained does not add to the patentability of the composition. Moreover, the source from which the said beta-glucan is obtained does not limit the claimed composition. Claim 52 which is drawn to the composition of claim 42, wherein said beta glucan is formulated for oral administration, is rejected as being anticipated by Wang et al., since applicant's claimed composition does not disclose any

ingredient or substance that renders it different from Wang et al.'s composition or unsuitable for oral administration (see abstract and example 1, col. 4, line 50 to col. 5, line 14).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein (US 5,980,918).

Claim 1 is a product-by-process claim wherein the applicant claims "A physiologically acceptable concentrated beta-glucan composition comprising a glucan having a mixed β(1,3)(1,4) linked glucopyranosyl backbone prepared in an alcohol free process in the absence of organic solvents, wherein said beta-glucan composition has a concentration greater than 15% by weight." In claim 2, applicant claims the composition of claim 1, wherein the concentration of the said beta glucan is greater than 68%. Dependent claims 12, 33 and 43 are drawn to compositions wherein the concentration of the said beta glucan is greater than 68%.

Klein discloses applicant's beta-glucan composition comprising a glucan having a mixed β(1,3)(1,4) linked glucopyranosyl backbone, wherein said beta-glucan composition has a concentration 0.5-15% by weight (see col. 3, lines 18-29, and abstract). It should be noted that applicant's composition of concentration greater than 15% (which includes 16%) also reads on Klein's composition of concentration about 15% which includes a composition of 16%.

The difference between applicant's claimed composition and the composition of Klein is the concentration in percent by weight of beta-glucan. However, Klein discloses that the beta-glucan can be used for healing burns and wounds and scarring (see abstract).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to prepare Klein's beta glucan compositions comprising mixed (1,3)(1,4) linked glucopyranosyl backbone of different percent concentration to be used for healing burns, wounds and scars, based on factors like severity of burns, wounds or scars.

One having ordinary skill in the art would have been motivated, to prepare Klein's beta glucan compositions comprising mixed (1,3)(1,4) linked glucopyranosyl backbone of different percent concentration to be used for healing burns, wounds and scars, based on factors like severity of burns, wounds or scars.

Response to Amendments

Applicant's arguments with respect to claims 1-52 have been considered but are not found convincing.

The applicant argues that the structure implied by the steps of preparing a concentrated beta-glucan in an alcohol-free process versus a process that uses alcohol precipitation is different. Applicant claimed composition thus differ from the composition of Wang, which uses an alcohol precipitation step. See, Wang, Abstract. Accordingly, Wang does not anticipate Claims 1-21 and 32-50. However, applicant has not provided any evidence that indicates that their composition is different from Wang et al.'s composition, especially since Wang et al.'s composition has the same molecular weight as applicant's. For example, applicant's beta-glucan is of high molecular weight, between about 400,000 and one million Daltons (see specification,

page 5, last line to page 6, lines 1-2) and Wang et al.'s also disclose beta-glucan with a molecular weight of 400,000 (4×10^5) Daltons (see abstract). Furthermore, applicant has not presented any evidence such as a side-by-side comparison of their beta-glucan composition versus Wang's et al.'s beta-glucan composition which shows that their composition is different because it is produced in an alcohol-free process.

The applicant argues that Wang et al. do not disclose a composition packaged and labeled as a dietaty supplement. Therefore, Wang et al. do not anticipate amended Claims 11-21. However, the said packaging, labeling and the intended use of the composition do not add to the patentability of the composition nor does it render the composition different.

The applicant argues that Wang et al.'s do not disclose a composition comprising β glucan that has been combined with a food product, and therefore cannot anticipate Claims 32 and 34-41. However, Wang et al.'s composition comes from and contains oats which is edible (a food) (see abstract and example 1, col. 4, line 50 to col. 5, line 14).

The applicant argues that Klein lacks any suggestion to modify the composition to increase the concentration of, or a reasonable expectation of success in modifying Klein, it cannot support a prima facie case of obviousness. However, Klein discloses that the beta-glucan can be used for healing burns and wounds and scarring, and it is obvious and common in the art to vary the concentration of an active ingredient (such as increasing the concentration of said active ingredient) based on factors like nature and severity of the burns, wounds or scars.
It should be noted that the claimed concentration of applicant's beta-glucan composition is substantially close to the concentration of Wang et al.'s beta-glucan composition (i.e., about 15% by weight compared to greater than 16% by weight).

The declaration under 37 CFR 1.132 filed 11/27/06 is insufficient to overcome the rejection of claims 1-52 based upon Wang et al. and Klein as set forth in the last Office action because: The declaration fails to set forth any evidence that indicates that applicant's composition is different from Wang et al.'s composition, especially since Wang et al.'s composition has the same molecular weight as applicant's. For example, applicant's beta-glucan is of high molecular weight, between about 400,000 and one million Daltons (see specification, page 5, last line to page 6, lines 1-2) and Wang et al.'s also disclose beta-glucan with a molecular weight of 400,000 (4×10^5) Daltons (see abstract). Furthermore, applicant has not presented any evidence such as a side-by-side comparison of their beta-glucan composition versus Wang's et al.'s beta-glucan composition which shows that their composition is different because it is produced in an alcohol-free process.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

Elli Peselev
Primary Patent Examiner
Art Unit 1623

June29, 2006.